UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, and SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare and Medicaid Services, Defendants.	Case No. _____ **ECF Case**

DECLARATION OF RICHARD O'NEAL IN SUPPORT OF PLAINTIFF'S ORDER TO SHOW CAUSE FOR PRELIMINARY INJUNCTION, TEMPORARY RESTRAINING ORDER, AND EXPEDITED BRIEFING SCHEDULE

I, Richard O'Neal, hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746, as follows:

1. My name is Richard O'Neal and I am the Vice President of Market Access at Regeneron. I make this Declaration in Support of Regeneron's Proposed Order to Show Cause for a Preliminary Injunction, Temporary Restraining Order, and Expedited Briefing Schedule. I am familiar with the facts and circumstances stated herein, which are based upon my personal

knowledge except where otherwise stated. If I were called upon to testify, I could and would testify competently as to the facts set forth herein.

2. I have been the Vice President of Market Access at Regeneron since March 2018. In this role, I am responsible for all aspects of Market Access including U.S. and Global Market Access and Reimbursement, Pricing & Contract Strategy, National and Regional Payer Engagement, Group Purchase Organizations, and Trade and Distribution.

3. I am a trained pharmacist, holding a registered pharmacist degree from St. Louis College of Pharmacy. Early in my career, I worked as both a retail and hospital pharmacist at Walgreen's Pharmacy and St. John's Mercy Hospital System. I then joined Express Scripts, a leading pharmacy benefit manager (PBM) in 1998, holding positions of increasing responsibility from Account Manager through Senior Director, Pharmaceutical Business Development. As the Express Scripts business grew, I was involved in multiple PBM acquisitions during that time. While I was at Express Scripts, I also obtained a Masters in Business Administration from Lindenwood University.

4. In 2003, I transitioned to the pharmaceutical industry and joined Amgen. My roles at Amgen grew in scope and responsibility during my 15-year tenure, including holding the position of Executive Director, National Accounts.

5. Most recently, I was Vice President at Axovant Sciences where I was responsible for developing the overall strategic payer access plan for the company. My team encompassed payer value, trade distribution, HUB patient support, contract management as well as national and regional account teams.

6. Like other drugs in the United States, certain Regeneron drugs are distributed pursuant to a "buy and bill" model. Under that model, each time a product changes hands, there is a change of title and a different price from the prior transaction in the chain.

7. Regeneron sells its "buy and bill" drugs to wholesalers (known as specialty distributors), which sell them to doctors (sometimes directly to doctors, and sometimes through Group Purchasing Organizations acting on behalf of groups of doctors). After purchase, doctors store the drugs for later administration to patients.

8. Later, when a doctor prescribes the stored drug, she administers the drug directly to Medicare beneficiaries. The doctor then seeks and obtains reimbursement from Medicare for the drug and its administration.

9. Currently, the Medicare reimbursement rate is tied to a drug's Average Sale Price (ASP).

10. The Medicare reimbursement rate is typically higher than a doctor's acquisition costs, *i.e.*, the price that a doctor pays to wholesalers to acquire and store a drug for later administration. As Medicare reimbursement rates increase or decrease, the difference between the reimbursement rate and a doctor's acquisition costs also increases or decreases. If the Medicare reimbursement rate falls below a doctor's acquisition costs, the doctor will no longer be able to prescribe and administer that drug to a Medicare beneficiary without incurring a financial loss.

11. My understanding is that on November 20, 2020, the Department of Health and Human Services, Centers for Medicare and Medicaid Services, issued an "interim final rule with comment period" entitled "Most Favored Nation (MFN) Model" (the "MFN Rule").

12. Under the MFN Rule, rather than determine reimbursement rates based solely on ASP, Medicare will use foreign prices to determine an "MFN Price" for a listed drug, which will

in turn be used to determine the "MFN Drug Payment Amount" for that drug. Medicare will then reimburse doctors the MFN Drug Payment Amount.

13. The MFN Price for a listed drug will be based on the lowest price paid for that drug by an OECD member country with a GDP per capita that is at least 60% of the U.S. GDP per capita.

14. In the first year of the MFN Rule's implementation, the MFN Drug Payment Amount will be 75% ASP and 25% MFN Price. In the second year, the MFN Drug Payment Amount will be 50% ASP and 50% MFN Price. In the third year, the MFN Drug Payment Amount will be 25% ASP and 75% MFN Price. In the fourth through seventh years, the MFN Drug Payment Amount will be 100% MFN Price.

15. If the MFN Rule is implemented, Regeneron will suffer significant, irreparable harm, for the following reasons.

16. Regeneron's product EYLEA® (aflibercept) Injection ("EYLEA"), which is used to treat wet age-related macular degeneration and other retinal diseases, is included in the MFN Rule's list of regulated drugs. Indeed, it is the first item on the MFN Rule's list of drugs purportedly with the highest annual Medicare Part B spending in 2019, and it is the only drug specifically named in HHS's Fact Sheet accompanying the MFN Rule.

17. At page 76207 of the MFN rule as published in the Federal Register, the MFN Rule includes a table providing, for each drug covered by the MFN Rule beginning January 1, 2021, the "Illustrative MFN Country," meaning "the country with the lowest GDP-adjusted country level price." The table also provides, for each covered drug, an "illustrative MFN price" for each quarter of 2019, which is "[b]ased on available international drug pricing sales and volume information for the calendar quarter for" the "Illustrative MFN Country."

18. For EYLEA, the MFN Rule provides that the "Illustrative MFN Country" is Norway.

19. Based on the methodology provided in the MFN Rule, and using the "illustrative MFN price" indicated for the fourth quarter of 2019 for EYLEA (*i.e.*, the price the government has calculated for EYLEA in Norway), I anticipate that the MFN Drug Payment Amount for EYLEA during implementation of the MFN Rule, beginning on January 1, 2021, will be lower than the current EYLEA reimbursement rate (based on ASP alone).

[redacted]

21. As a result of these reductions, the reimbursement rates for EYLEA will fall below doctors' acquisition costs for EYLEA beginning January 1, 2021.

22. In light of doctors' reimbursement rates for EYLEA falling below doctors' acquisition costs beginning January 1, 2021, one of several things will happen.

23. First, a doctor who currently purchases and prescribes EYLEA will instead purchase and prescribe a competitor product that is not subject to the MFN Rule and thus not subject to a reduced reimbursement rate, much less one lower than the doctor's acquisition costs.

24. For example, doctors have treated wet age-related macular degeneration using bevacizumab (branded Avastin®) compounded and off-label—*i.e.*, for an indication for which it has not received FDA approval. Bevacizumab is not on the MFN list for ophthalmological uses, and off-label uses are not covered by the MFN Rule. Indeed, since the MFN Rule's issuance, Regeneron has already begun receiving questions from doctors and organizations that advocate on

behalf of doctors regarding the imminent lower reimbursement rate for EYLEA and the looming need to switch patients from EYLEA to off-label Avastin.

25. The MFN list also does not include Beovu® (brolucizumab-dbll) injection, which was approved in 2019 to treat wet age-related macular degeneration. And additional competitor drugs may be approved in the future and not be included on the MFN list. As with off-label Avastin, doctors will prescribe these non-MFN drugs over EYLEA if the EYLEA reimbursement rate is reduced by the MFN Rule, particularly to a rate lower than doctors' acquisition costs.

26. Even if the MFN Rule were eventually enjoined and reimbursement rates for EYLEA returned to their current levels, at least some patients who were switched from EYLEA to off-label Avastin (or other drugs) would be unlikely to return to EYLEA.

27. Doctors are also highly unlikely to start new patients on EYLEA, as opposed to competitor drugs, if they know that, in the future, they will be unable to prescribe EYLEA because the EYLEA reimbursement rate will fall below their acquisition costs. At least some of these patients are unlikely to be switched over to EYLEA if the MFN Rule were eventually enjoined.

28. Fewer prescriptions for EYLEA, because doctors are purchasing and prescribing competitor drugs, will mean lost sales and reduced revenue from EYLEA.

29. Alternatively, to avoid sales lost to off-label Avastin (or other competitor drugs not on the MFN list), Regeneron would be forced to lower the price of EYLEA. Given Regeneron's existing contracts with suppliers and providers, Regeneron could not implement a price reduction prior to January 1, 2021, because Regeneron cannot break those contracts. And even if Regeneron were able to break or renegotiate those contracts, the result would be reduced revenue for Regeneron, as well as reputational and competitive injury resulting from Regeneron's need to renegotiate contracts while competitors without MFN-listed drugs need not do so.

30. Regeneron cannot raise EYLEA's MFN Price by altering prices in foreign countries. Outside the United States, EYLEA is marketed by Bayer, which has a license to Regeneron's intellectual property and solely determines pricing for EYLEA consistent with other nations' policies. Regeneron does not and cannot control the pricing of EYLEA outside the United States.

31. EYLEA is Regeneron's top-selling product. U.S. EYLEA net product sales represented 70.8% of Regeneron's 2019 total revenue.

32. While it is difficult to calculate with precision, I estimate that implementation of the MFN Rule on January 1, 2021, will result in a reduction in Regeneron's annual revenue in the first three years of the seven-year MFN model by the following approximate amounts per year:

34. Regeneron routinely devotes over 30% of its revenue to research and development activities.

35. Because of the negative effect of the MFN Rule on Regeneron's revenue, and in particular the reduction in revenue from EYLEA, implementation of the MFN Rule will reduce Regeneron's investment in research and development.

36. Even a temporary reduction in research and development projects irreparably disrupts ongoing time-sensitive scientific work, and because innovation begets innovation, the failure to innovate now irrevocably results in cumulatively less innovation later.

37. A failure to invest in research and development also irreparably harms Regeneron vis-à-vis its competitors, especially those whose products are not included in the MFN Rule.

38. The aforementioned information is highly confidential, internal information concerning Regeneron's financial projections and business strategy. Public disclosure of this information would severely damage Regeneron's competitive standing and financial well-being.

I declare under penalty of perjury that the foregoing is true and accurate to the best of my knowledge. Executed this 10th day of December, 2020, at Tarrytown, New York.

Richard O'Neal